

Compulsory Licensing for Public Health

*A Guide and Model Documents for
Implementation of the Doha
Declaration Paragraph 6 Decision*

Frederick M. Abbott

Rudolf V. Van Puymbroeck



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THE WORLD BANK
Washington, D.C.

WORLD BANK
Global HIV/AIDS Program



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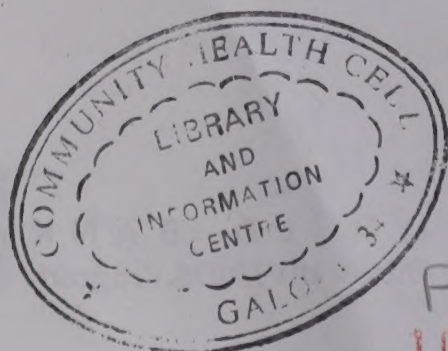
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Foreword

The World Trade Organization's decision of August 30, 2003 on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health was intended to facilitate access to medicines in developing countries. The decision, which was the outcome of nearly two years of strenuous multilateral negotiations, was widely reported in the international press and in professional journals.

Despite all this attention, the decision has still not been used to bring affordable, life-saving medicines to countries that, judging by the severity of their public health challenges, need them desperately. This is an extraordinary fact, and one worthy of further inquiry. One reason for the lack of followup action may be that the subject is inherently difficult: it deals with the intersection of the law of patents, an arcane discipline, and the international trade regime—both in its legal rules and in the practical conduct of state-to-state cooperation. The recognition of this inherent complexity led to the idea of producing a guide with actual model legal instruments and draft statutory provisions to facilitate the implementation of the decision.

The project was undertaken and managed by Rudolf V. Van Puymbroeck, Lead Counsel in our Legal Advisory Services group, when he served as full-time legal adviser with the World Bank's Global HIV/AIDS Program. Professor Frederick M. Abbott, Edward Ball Eminent Scholar and Professor of International Law at Florida State University College of Law, provided the drafts of the model legal documents and detailed commentary.

In the summer of 2004 an advanced draft was circulated for comment to a large number of legal practitioners, academics, international organizations, non-governmental organizations, representatives of the research-based pharmaceutical industry and of generic pharmaceutical manufacturers, and far-flung specialized staff of the World Bank. Much useful feedback was received and duly incorporated. The result is this Guide that you now have before you.

I sincerely hope that it will serve policymakers and their legal advisers in many developing countries in confronting effectively, and ultimately overcoming, the significant public health challenges they face, including, especially, the scourge of HIV/AIDS.

Roberto Dañino

Senior Vice President and General Counsel

The World Bank

April 2005

Abstract

The Doha Declaration on the TRIPS Agreement and Public Health (in its Paragraph 6) recognized that developing countries with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. The WTO's decision of August 30, 2003 set up a system intended to overcome these difficulties. The present work is a guide to the implementation of that system.

The first part gives the reader an understanding of the issues involved; the second part provides model documents for use by governments. Four model instruments of notification are included: three for notification of the WTO as required by the Decision and one for notification of the patent or right holder pursuant to Article 31 of the TRIPS Agreement. Because most countries will have to amend their legislation (typically their patent law) to implement the system, model amendment provisions have been provided both for exporting countries and for importing countries. All model documents contain their own detailed commentary.

Acknowledgments

The authors wish to acknowledge the support and unfailingly helpful critiques they received from a great many people in the course of this project, particularly those who provided written comments on the discussion draft circulated in May/June 2004. While there are too many individuals to be named separately, we say thank you to each and every one.

We wish to dedicate a special word of gratitude to two individuals without whom this work would not have been possible.

Dr. Debrework Zewdie, Director of the World Bank's Global HIV/AIDS Program, gave Rudolf V. Van Puymbroeck the opportunity of a year-long immersion in the legal issues associated with HIV/AIDS, and it was during this time that the project was conceived and initiated.

Critical financing for this work, and for the larger enterprise of initiating work on legal reform for effective action against HIV/AIDS, was provided by James D. Wolfensohn, president of the World Bank, who, as usual, was one step ahead of the rest of us in diagnosing the problem and contributing to the solution.

Introduction

In its 4th Global Report, UNAIDS draws attention to the abysmal rate of treatment for HIV/AIDS in low- and middle-income countries: of the 5 to 6 million people urgently in need of antiretroviral medicines, only some 400,000 were actually receiving them at the end of 2003.¹

There are many and highly diverse reasons why such an extraordinarily large number of people in developing countries who require treatment are not receiving it;² the lack of availability and the high cost of medicines to treat HIV/AIDS and associated opportunistic infections are two of them.³

1. UNAIDS, *2004 Report on the Global AIDS Epidemic* 101 (UNAIDS 2004) (hereafter UNAIDS, *4th Global Report*). See also World Health Organization, *The World Health Report 2004* 7 (WHO 2004), (hereafter WHO, *The World Health Report 2004*) pointing out, *inter alia*, that treatment coverage for the Africa Region is only 2 percent. A joint media release of UNAIDS, WHO, GFATM and the U.S. Government dated January 26, 2005 put the number of individuals receiving antiretroviral treatment at the end of 2004 at 700,000, available at: <<http://www.unaids.org/en/media>>.

2. See generally *The World Health Report 2004*; WHO and UNAIDS, *Treating 3 Million by 2005: Making it Happen* (WHO 2003). See also The World Bank, *The Millennium Development Goals for Health: Rising to the Challenges*, Part II (2004) (hereafter World Bank, *Rising to the Challenges*).

3. UNICEF, UNAIDS, WHO and Médecins Sans Frontières, *Sources and prices of selected medicines and diagnostics for people living with HIV/AIDS* 1 (WHO 2004), "The high price of many of the HIV-related medicines and diagnostics offered by common suppliers—especially antiretroviral and anti-cancer medicines—is one of the main barriers to their availability in developing countries." See also UNAIDS, *4th Global Report*, *supra*, n. 1, at 135, "I can take these tablets, because on the salary I earn as a judge, I am able to afford their cost . . . In this I exist as a living embodiment of the inequity of drug availability and access in Africa . . . My presence here embodies the injustices of AIDS in Africa because, on a continent in which 290 million Africans survive on less than one US dollar a day, I can afford monthly medication costs of about US\$400 per month." (Mr. Justice Edwin Cameron, High Court of Johannesburg, South Africa); Sonia Ehrlich Sachs and Jeffrey D. Sachs, *Too Poor to Stay Alive in AIDS and South Africa: The Social Expression of a Pandemic* 3–4 (Kyle D. Kauffman & David L. Lindauer, eds., Palgrave Macmillan 2004);

Because of the downward effect on prices resulting from the introduction of generic drugs in pharmaceutical markets,⁴ the impact of patents on the price of HIV/AIDS-related medicines and related supplies, and essential medicines in general, has come under increased scrutiny.

As most countries are members of the World Trade Organization (WTO), the patent regime of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) provides in effect a global standard.⁵ It contains important flexibilities, which have been clarified and expanded in the WTO's 2001 Declaration on the TRIPS Agreement and Public Health (Doha Declaration)⁶ and its Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of August 30, 2003 (Paragraph 6 Decision or the Decision).⁷

The international community has reacted favorably to the Doha Declaration and the Decision. The World Health Assembly, the highest organ of the World Health Organization (WHO), has adopted resolutions urging all member states to adapt national legislation, whenever necessary, to use "to the full" the flexibilities contained in the TRIPS Agreement.⁸ A number of countries are now preparing the necessary legislative steps to implement the Doha Declaration and the Paragraph 6 Decision, and some have already done so.⁹

This Guide has been prepared to facilitate the implementation of the Decision.

Robert Lewis-Lettington & Peter Muniy, *Willingness and Ability to Use TRIPS Flexibilities: Kenya Case Study* 13–14 (Department for International Development 2004); and Robert Lewis-Lettington & Chikosa Banda, *A Survey of Policy and Practice on the Use of Access to Medicines-Related TRIPS Flexibilities in Malawi* 15 (Department for International Development 2004).

4. Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* 37 (September 2002); Médecins Sans Frontières, *Surmounting Challenges: Procurement of Antiretroviral Medicines in Low- and Middle-Income Countries* 7–8 (Médecins Sans Frontières, WHO, UNAIDS 2003). As noted in these studies and others, competition from generic manufacturers is not the only reason why prices of antiretrovirals have come down. Other important factors are: (i) government policies (particularly with respect to procurement, taxation, local production, and subsidies); (ii) deep price discounts by the major pharmaceutical companies (especially since the launching of the U.N.-sponsored Accelerating Access Initiative in May 2000) and medicine donation programs; (iii) private Foundation initiatives (for example, the Clinton Foundation HIV/AIDS Initiative, the Bill and Melinda Gates Foundation's Global Health Programs); and (iv) increased public attention and advocacy. See also, *Rising to the Challenges*, *supra*, n. 2, at 117–125. Facilitating policies and programs of international organizations (for example, WHO's Pre-Qualification Scheme for HIV Drugs, the World Bank's Multi-Country and Multi-Sector HIV/AIDS Programs) and the establishment and operation of the Global Fund to Fight AIDS, Tuberculosis and Malaria, played important supporting roles.

5. TRIPS Agreement, Part II, Section 5, available at: <<http://docsonline.wto.org>>.

6. WT/MIN(01)/DEC/2, available at: <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm>.

7. IP/C/W/405, available at: <http://www.wto.org/english/tratop_e/trips_e/t_news_e.htm>.

8. Resolutions WHA56.27 (2003) and WHA57.14 (2004), available at <<http://www.who.int/governance/en/>>.

9. On May 14, 2004, Canada enacted Bill C-9 to amend the Patent Act and the Food and Drugs Act with the express purpose of facilitating implementation of the Paragraph 6 Decision (hereafter referred to as "Bill C-9," available at <<http://www.aidslaw.ca>>). In Norway, following the adoption on December 19, 2003 of an authorizing amendment of the Patents Act, the government has, by Royal Decree of May 14, 2004, adopted regulations to implement the Paragraph 6 Decision (available at: <<http://www.dep.no/ud/engelsk/p2500832>>). The government of the United Kingdom has expressed its intent to amend its patent legislation and will support an EU-wide resolution on the matter (Department for International Development, *Increasing access to essential medicines in the developing world: UK Government policy and plans* 34, available at: <<http://www2.dfid.gov.uk/pubs>>). On February 19, 2004 the ACP-EU Parliamentary Assembly adopted a Resolution that, among other things, calls upon the European Commission and

Structure

This Guide is structured as follows:

Part I gives a concise explanation of the Doha Declaration and its clarification of the flexibilities inherent in the TRIPS Agreement patent regime. It also lays out the system of substantive and procedural requirements established by the Decision (the System) in sufficient detail so as to provide a proper context for the model documents presented in Part II.

Part II provides model documents to implement the System. They consist of model notifications to the WTO and to right holders, and model legislative and regulatory provisions that may be necessary for the domestic application of the System in both exporting and importing countries. A detailed commentary is provided after each text.

The Appendixes provide further resource materials. The key WTO texts that are dealt with in the Guide are the Paragraph 6 Decision, the General Council's Chairperson's Statement, the Doha Declaration, and Article 31 (Other Use without Authority of the Right Holder) of the TRIPS Agreement. They are reproduced in Appendixes A, B, C, and D respectively.

Caution

At the outset, it is important to state what this Guide does not do.

First, it does not engage in a discussion about the merits or demerits of intellectual property rights, of the TRIPS Agreement patent regime, or of its application in developing countries. The Guide takes as its starting point the Paragraph 6 Decision—a decision of all the WTO member countries.

Second, this Guide takes no position on the wisdom or desirability of granting a compulsory license under the Decision in any particular case. Countries vary enormously with respect to their supply situation for medicines, the policy objectives and legal framework of their intellectual property rights regime, and their public health systems and policies. Hence, whether or not a country should avail itself of the System is a matter to be decided by its authorities after careful consideration of all the circumstances.

Third, this Guide can only provide a starting point. The actual implementation of the Paragraph 6 Decision will take place within the contours of each country's existing legislative and regulatory framework, practice and jurisprudence. The authorities of each country will have to work with their own legal experts to arrive at a solution that is right for their situation.

member states to respect, promote and support the implementation of the Doha Declaration and that calls on all countries with manufacturing capabilities to carry out the agreement quickly and without any further restrictions and fully respecting the Doha Declaration (paragraphs 21 and 25) (available at: <<http://www.europarl.eu.int/intcoop/acp>>). On February 24, 2004, representatives of states and governments from Europe and Central Asia adopted the Dublin Declaration on Partnership to Fight HIV/AIDS in Europe and Central Asia, in which they agreed, among other things, on action to ensure early implementation of the Paragraph 6 Decision (paragraph 22) (available at: <<http://www.eu2004.ie>>). On October 29, 2004 the European Commission proposed a regulation to implement the Paragraph 6 Decision (available at: <http://europa.eu.int/comm/trade/issues/global/medecine/pr291004_en.htm>). The Netherlands published new rules on December 21, 2004 (available at: <<http://www.cptech.org/ip/health>>), and draft amendments of the patent law are under consideration in Switzerland (available in French at <<http://www.ige.ch/F/jurinfo/documents/j10013f.pdf>>).

PART I

The Doha Declaration and the Paragraph 6 Decision— A Concise Explanation

A compulsory license is a legal vehicle whereby a government grants to itself or to a third party the right to produce or to import a patented product without authorization of the patent holder or right holder (both are hereafter referred to as the “right holder”).¹⁰ Their issuance is the subject of detailed conditions. For WTO member countries, a mandatory set of conditions is set out in Article 31 of the TRIPS Agreement. A country’s domestic legislation may also contain other, additional conditions affecting the issuance of compulsory licenses.

Among the conditions set out in Article 31 of the TRIPS Agreement, the following are especially relevant in the context of the Paragraph 6 Decision:

- the grantee must first have made efforts, for a reasonable time, to negotiate authorization from the right holder on “reasonable commercial terms and conditions” (Article 31(b));
- Members may dispense with this requirement, however, in the case of a “national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.” (Article 31(b));
- the use authorized by the compulsory license must be “predominantly for the supply of the domestic market” (Article 31(f));¹¹ and

10. For a fuller treatment, see The World Bank, *Battling AIDS: A Decision-Maker’s Guide to the Procurement of Medicines and Related Supplies*, 119 *et seq.* (Yolanda Tayler, ed., The World Bank 2004) (hereafter *Battling AIDS*), available at <<http://siteresources.worldbank.org/INTPROCUREMENT/Resources/Technical-Guide-Procure-HIV-AIDS-Meds.pdf>>. In this Guide, as in *Battling AIDS*, government use licenses and compulsory licenses granted to third parties are both referred to as “compulsory licenses,” unless otherwise indicated in the text.

11. The predominant-supply-of-the-domestic-market requirement does not apply to compulsory licenses granted to remedy anti-competitive practices (TRIPS Agreement, Article 31(k)). Thus, when an exporting Member grants a compulsory license to remedy an anti-competitive practice it does not act under the Decision because it does not take advantage of the waiver of Article 31(f) established by the Decision. It instead acts under a pre-existing right in the TRIPS Agreement to authorize exports to address anti-competitive practices. In such cases, the importing Member does not need to comply with the notification and other requirements set out in the Decision.

- adequate remuneration must be paid to the right holder (Article 31(h)).¹²

As part of the launching of a new multilateral work program of reform and liberalization of trade policies at the WTO's Ministerial Conference in Doha, Qatar, an agreement was reached among all WTO Members on the application of the TRIPS Agreement to public health.¹³ This Declaration contains important provisions for the interpretation and application of Article 31 of the TRIPS Agreement.

In its paragraph 4, the Doha Declaration formally affirms that:

- "... the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health;"
- "... the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all;"
- "... WTO Members [have the right] to use, to the full, the provisions of the TRIPS Agreement, which provide flexibility for this purpose."

The Doha Declaration then explains in its paragraph 5 that, within the context of the TRIPS Agreement, "these flexibilities include":

- "... the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted;"
- "... the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."

Paragraph 6: A Problem Left Unresolved¹⁴

The Doha Declaration left an important problem unresolved. It recognized that "WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement" and the Ministers charged the Council for TRIPS to find "an expeditious solution" to the problem (Doha Declaration, Paragraph 6).

If a developing country does not have the industrial capacity to produce a particular medicine itself under a compulsory license, or if it has insufficient capacity, it has no

12. "Adequate remuneration" is defined with respect to the circumstances of each case, "taking into account the economic value of the authorization." (Article 31(h)).

13. The agreement was embodied in a Declaration adopted by the Ministerial Council on November 14, 2001. *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2, available at: <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm>.

14. This section and the following draw on Rudolf V. Van Puymbroeck, *Exportation of Drugs under Compulsory Licenses: The WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the Trips Agreement and Public Health*, available at: <http://www1.worldbank.org/hiv_aids/docs/GHAPnote10.03.03.pdf>.

recourse but to import the drug. However, if it wishes to import a generic drug that is produced under compulsory license, the amount of product that is available for export is limited by the “predominantly for the supply of the domestic market” condition in paragraph (f) of Article 31 of the TRIPS Agreement.

Countries like India and Brazil, which have a domestic generics industry, constitute—by themselves—large markets, and hence the “non-predominant part” of production authorized under a compulsory license could still be substantial.¹⁵ Any export of that non-predominant part would not be affected by the Paragraph 6 Decision. However, that amount may not be sufficient to satisfy all needs if many developing countries start importing such drugs in large quantities, which appears to be virtually inevitable as they are faced with an ever growing need to provide access to essential medicines.

Also, companies in other countries, developing or industrialized, that have the capability to produce quality generics may wish to manufacture expressly for export to developing countries. In order to permit the flow of such medicines to developing countries, a solution to the limitations of Article 31 of the TRIPS Agreement had to be found.

The Paragraph 6 Decision

Finding a solution to this problem was not easy. After nearly two years of hard negotiations, a compromise acceptable to the industrialized and to the developing countries was finally achieved and adopted as a decision of the WTO’s General Council.¹⁶

The Decision is couched in the form of the waiver of two provisions of Article 31 of the TRIPS Agreement: (a) with respect to the exporting country, a waiver of the predominantly-for-the-domestic-market limitation; and (b) with respect to the importing country, a waiver of the adequate remuneration requirement. There is also a specific waiver of the former of these provisions, together with certain other flexibilities, for certain regional trade arrangements.

While the full text of the Decision should be consulted for all particulars, the system that both the exporting country and the importing country need to apply in order to benefit from the waivers can be summarized as follows.¹⁷

15. The TRIPS Agreement patent regime became applicable to India as of January 1, 2005. Brazil amended its law to provide for pharmaceutical product patent protection effective May 15, 1997.

16. The General Council, which is composed of representatives of all WTO member countries, exercises the functions of the Ministerial Council when the latter is not in session, as well as other functions assigned to it under the WTO Agreement.

17. The Decision is available at <http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm>. For ease of reference, the Decision and the Chairperson’s Statement are also provided in Appendixes I and II, respectively. Extensive treatment of the Decision and interpretative guidance may be found in, *inter alia*, Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99(2) Am. J. of Intl. L. (forthcoming 2005); Carlos M. Correa, *Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, EDM Series No. 16 (WHO 2004); Paul Vandoren & Jean Charles Van Eeckhoutte, *The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Making it Work*, 6 J. World Intellectual Property 779 (2003).

Waiver of the Predominant Domestic Supply Requirement

The predominant domestic supply requirement is waived with respect to the compulsory license granted by the exporting country if the following conditions are met:

- (a) the importing country must be an “eligible importing Member,” which means that it must be a least-developed country,¹⁸ or any other member country of the WTO that has notified the Council for TRIPS that it intends to use the system as an importer;
- (b) the eligible importing Member must provide a notification to the Council for TRIPS which contains: (i) the name and expected quantity of the product (or products) needed; (ii) confirmation that it has established (in one of the ways set out in the annex to the Decision) that it has no or insufficient manufacturing capacity for the product in question—but least-developed countries are exempt from this requirement; and (iii) confirmation that the country has granted or will grant a compulsory license in accordance with Article 31 of the TRIPS Agreement if the pharmaceutical product is on-patent in its territory;
- (c) the exporting country must notify the Council for TRIPS of the grant of the compulsory license, including the conditions attached to it (see below), and providing information about the licensee, the product(s) and the quantity(ies) for which the license was granted, the country(ies) of destination, the duration of the license, and the website that provides specified information about the license (see below); and
- (d) the compulsory license must be subject to the following conditions: (i) only the amount of product necessary to meet the needs of the eligible importing country may be produced under the license and all that production must be exported to that country; (ii) all products so produced must be clearly identified under the system set up under this Decision through specific labeling or marking—the products should be distinguished through special packaging and/or special coloring or shaping of the products themselves, provided the distinction is feasible and has no significant impact on the price; and (iii) prior to shipment, the licensee must post on a website (which may be a WTO website) the quantities being supplied to each destination and the distinguishing features of the product.

Partial Waiver of the Adequate Remuneration Requirement

Paragraph (h) of Article 31 of the TRIPS Agreement provides that “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.”

In order to avoid double compensation, this obligation is waived in the importing country provided that adequate remuneration was paid in the exporting country. The Decision specifies that the remuneration to be paid to the right holder in the country of export must take into account “the economic value to the importing country of the use

18. The WTO refers to the United Nations’ designation of least-developed countries. The list is available at <http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm>.

that was authorized in the exporting country.” No clarification was provided on the application of this standard.

Supplemental Provisions of Note

While the above-described mechanism constitutes the essence of the Decision, certain supplemental provisions and requirements must be noted:

The Decision covers not only patented products (and products manufactured through a patented process) of the pharmaceutical sector, but also the active ingredients necessary for their manufacture, as well as diagnostic kits necessary for their use.

Importing countries using the System must take reasonable measures (within their means and proportionate to their administrative capacities and the risk of trade diversion) to prevent re-exportation, and all WTO Members must provide effective legal means to prevent the importation and sale of goods produced under the System that are the subject of trade diversion.

Re-exportation is, however, permitted in the case of certain intra-regional trade agreement (RTA) transactions. When certain conditions are satisfied, Paragraph 6 of the Decision waives Article 31(f) to allow the re-exportation of pharmaceutical products imported under a compulsory license to other developing or least-developed members of the RTA that experience the same public health problem. The conditions are that: (a) the RTA must be sanctioned by the WTO;¹⁹ and (b) at least half of the Members must be least-developed countries listed as such by the United Nations on the date of the Decision.²⁰

In practical application, this provision is of benefit to trade groupings in Africa. It allows them to make use of economies of scale by bulk procurement by one (or more) of the members, and it facilitates the importation of component materials, formulation into finished products, and export to countries of the RTA. In the event of re-exportation to members of the RTA, Paragraph 6 of the Decision does not impose any obligation of notification to the WTO. As an additional flexibility, the regional organization may make the required notification to the WTO of actual importation on behalf of all the importing members of the RTA.²¹

For the avoidance of doubt, Paragraph 6 clarifies that this waiver for RTAs is not intended to “prejudice the territorial nature of the patent rights in question.” This means that there still needs to be a voluntary or compulsory license in the importing Members of the RTA if the product is under patent there (unless the importing member is a least-developed country electing not to enforce relevant patents).

More generally, the Decision also contains provisions encouraging the development of regional patent regimes, technology transfer, technical assistance, and capacity building. The system established by the Decision is to be reviewed annually by the Council for TRIPS, which must report on it to the General Council. Negotiation of a formal amendment of the

19. Meaning “a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation on Developing Countries” (Paragraph 6 Decision, paragraph 6(i)).

20. The actual text says “. . . countries *presently* on the United Nations list of least-developed countries . . .” (emphasis added) (Paragraph 6 Decision, paragraph 6(i)).

21. See the Decision, at footnote 4.

TRIPS Agreement based “where appropriate” on the Decision was to be started by the Council for TRIPS by December 31, 2003.²²

An Annex to the Decision provides that least-developed countries are automatically deemed to have no or insufficient manufacturing capacity in the pharmaceutical sector and provides guidelines to be used by other developing countries in establishing that they have no or insufficient manufacturing capacity for the product(s) in question.

Finally, it is important to note that the Decision was issued with an accompanying statement of the Chairperson of the General Council. That statement purports to represent key understandings of the member countries with respect to the Decision and the way in which the Decision is to be interpreted and implemented. These understandings deal with essentially four things:

- the need for Members to implement the Decision in good faith to protect public health and not to pursue industrial or commercial policy objectives;²³
- guidelines to avoid trade diversion;
- ways in which the WTO Members will be informed about the operation of the system and ways in which issues can be raised and resolved; and
- the countries that have agreed entirely to opt out of the System as importers or that will apply the system to import only in situations of national emergency or other circumstances of extreme urgency.

The legal significance of the Chairperson’s statement is unclear. However, as a practical matter, countries seeking to avail themselves of the System would be well-advised to make sure that their implementation of the System is consistent with the statement. This should not add any significant burden.

22. A start was made, but progress has been slow.

23. While the need to implement the Decision in good faith to protect public health is clear enough, the admonition to Members not to use the Decision to pursue industrial or commercial policy objectives is, under the circumstances, less so. To impose as a consequence, for example, price caps on exported generic products as was done in the Canadian legislation (*supra*, n. 9) appears questionable: The issue should not be whether “the agreement is commercial in nature” (*see* Bill C-9, Section 2.17(1))—the Decision relies on private commercial enterprises to produce and sell generics for export through commercial arrangements—but whether the *exporting country* uses the Decision to further its own national industrial or commercial policy objectives.

PART II

Model Legal Documents

This Part consists of six model legal documents to assist countries in implementing the Decision. Countries will need to adapt them to their own circumstances, but every effort has been made to provide, through these model documents, a convenient starting point for implementation of the Paragraph 6 Decision in a manner that is consistent with the letter and the spirit of the Decision and the Doha Declaration.

Documents 1, 2 and 3 are model notifications to the WTO required by the System. Document 4 is a model notification that is not required by the terms of the Paragraph 6 Decision but that is mandatory under Article 31 of the TRIPS Agreement; it is included here to ensure that this obligation is not overlooked. Alternative clauses are provided to reflect possible choices or different situations.

Documents 5 and 6 provide model provisions for the legislative or regulatory amendments that may be required in, respectively, the exporting country and the importing country.

It is important to note that Documents 5 and 6 are not intended as a substitute for complete national government use and compulsory licensing legislation or regulation. For WTO Members, Article 31 of the TRIPS Agreement generally establishes the conditions under which government use and compulsory licenses may be granted. Thus, for example, such licenses must be considered on their individual merits (Article 31(a)), must be non-exclusive (Article 31(d)), and they are subject to limitations on assignment (that is, they are non-assignable except with the part of the business or goodwill which enjoys use of the license). Article 31(l) establishes conditions with respect to the treatment of dependent patents. Article 31 also addresses review of compulsory licensing decisions. This Guide is limited to facilitating the implementation of the Paragraph 6 Decision—further information on the requirements of Article 31 of the TRIPS Agreement is available from other sources.²⁴

Explanatory comments are provided in a separate section under each document.

The term “Member” in this text refers to member countries of the WTO.²⁵

24. See for example, UNCTAD/ICTSD, *Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement*, Part 2.5.8, available at: <<http://www.iprsonline.org>>.

25. The WTO has 148 members (<<http://www.wto.org>>, accessed January 12, 2005). The membership of the World Bank, as at January 12, 2005, stands at 184 countries.

Notification By Developing Country Member To Council For TRIPS Of Intention To Use System As Importer

Document 1

**Notification to Council for TRIPS pursuant to General Council Decision
of August 30, 2003 on Implementation of Paragraph 6 of the Doha Declaration
on the TRIPS Agreement and Public Health**

[Member name] hereby notifies the Council for TRIPS of its intention to use the system established by the August 30, 2003 Decision of the General Council on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, without limitation or restriction, as an importer.

This notification shall remain in force and effect unless and until modified or withdrawn by [Member].

Date of notification:

Commentary

Paragraph 1(b) of the Decision requires a one-time notification to the TRIPS Council of intention to use the system as an importer. However, least-developed country Members are automatically understood to be eligible importing Members and are not required to file a one-time notification.

The notification establishes a developing country Member as an “eligible importing Member.” The notifying Member has the option to indicate that it will use the system “in whole,” or in a “limited way.” By way of illustrating a “limited way,” an example is provided in the Decision of using the system “only in the case of a national emergency or other circumstance of extreme urgency or in cases of public non-commercial use.”

There is no *a priori* reason to self-impose a limitation on use of the system as an importer, and hence the draft notification contemplates notification of intent to use the System without restriction or limitation. The text of the Decision provides further that “a Member may notify *at any* time that it will use the system in whole or in a limited way.” (emphasis added)²⁶ This indicates flexibility to make subsequent modifications to the notification.²⁷

For importing Members that are not least-developed countries as recognized by the WTO,²⁸ a compulsory license authorizing importation will be required for products under patent in the importing Member. There may be limitations in national compulsory licensing law regarding the circumstances in which a license may be issued, such as a limitation framed along the lines of the examples set out in the Decision (emergencies, public non-commercial use, and so on and so forth). Limitations in national law may be different in respect to “government use” and third party licensing. There is no legal requirement to limit the notification to the TRIPS Council to those options that are presently open in national law. A notification of intention to use the system “in whole” from a Member with limited options in national law would be understood as subject to whatever limitations may exist under national law. It would not operate to eliminate restrictions under national law because the grant of a compulsory license for import under the system would still take place in accordance with the provisions of national law.

Footnote 2 to Paragraph 1(b) of the Decision provides that “It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.” Therefore, a Member may transmit this notification to the TRIPS Council prior to discussion with or approval by any body at the WTO, including the TRIPS Council.

26. Paragraph 6 Decision, paragraph 1(b).

27. At the time of the Decision, a number of countries agreed not to make use of the System as importers (in whole or in part). Some others made statements to this effect in connection with the Chairperson’s statement. The flexibility noted in the text may not apply to these countries.

28. *See supra*, n. 18.

Importation under the Paragraph 6 Decision

*Notification by Least-Developed
Country Member*

Document 2

Notification of Importation under Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health

Paragraph 1:

Based on its present evaluation of its public health needs, [Member] expects to import [quantity(ies)] of [pharmaceutical product name(s)]. However, because it is not possible to predict with certainty the extent of its public health needs, [Member] reserves the right to modify the foregoing estimate as necessary or appropriate.

Paragraph 2:

Alternative 1: There is no patent on [pharmaceutical product(s) name(s)] in [Member]. This notification is made because [pharmaceutical product(s) name(s)] is (are) under patent in the country of export.

Alternative 2: Pursuant to Paragraph 7 of the Doha Declaration and implementation thereof by the TRIPS Council (Decision of the Council for TRIPS of 27 June 2002), [Member] has decided that it will not enforce rights provided under Part II Section 5 of the TRIPS Agreement that may have been granted within its territory with respect to [pharmaceutical product name(s)].

(continued)

Alternative 3: [Member] [intends to issue] [has issued] a license for the importation and distribution of [pharmaceutical product(s) name(s)] without the consent of the patent holder in accordance with the provisions of Article 31 of the TRIPS Agreement and the Decision. Pursuant to paragraph 3 of the Decision, remuneration to the patent holder shall be determined and paid in [country of export].

Date of notification:

Commentary

Paragraph 1

The Decision requires notification of the names and “expected” quantities of the pharmaceutical products needed. The objective of this provision is to discourage production and export of product that might be diverted to third country markets. However, in many contexts—such as in HIV/AIDS treatment—it may be very difficult to provide concrete estimates of quantities needed over time, and the requirement of providing an estimate was presumably not intended to bind the exporting and importing Members to a set production amount. The objective of the System is to allow Members to satisfy their legitimate public health needs. For this reason, under the notification, it is recommended that a Member expressly reserve the right to revise the expected quantities to be imported.

The Decision does not establish any form or template for the notification of expected quantities. A Member might elect to indicate an aggregate “amount” of product to be imported over the duration of a license, or it might elect to indicate the amount it expects to import on a periodic basis (for example, on an annual or quarterly basis). It may be appropriate to refer to “expected quantities” on a more subjective basis, such as “a quantity of pharmaceutical product ‘x’ sufficient to treat ‘y’ patients over ‘z’ period.” This might be a useful approach if, for example, there are different dosages and/or forms of administration of the product and the way in which orders for the product will be placed is not readily predictable.

Paragraph 2

Three alternatives are provided to deal with three possible fact situations: (1) the pharmaceutical product in question is not under patent in the importing country; (2) as a WTO least-developed country Member, the country has decided to exercise its right not to enforce pharmaceutical patents; and (3) the importing country, in application of its patent law, will provide a compulsory license.

Alternative 1:

This is straightforward and requires no explanation. It is of interest to note, though, that even if the pharmaceutical product in question is not under patent in the importing country, the notification of actual importation under the System is still required if the conditions to which the Decision applies pertain in the exporting country (that is,

the amount of product needed cannot be exported under the predominantly-for-the-domestic-market restriction in Article 31(b) of the TRIPS Agreement, or export of the product is not an exercise of an anti-competitive remedy under Article 31(k) of the TRIPS Agreement).

Alternative 2:

This notifies of the intention not to enforce relevant patents. Pursuant to paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health and implementing decisions by the TRIPS Council²⁹ and General Council,³⁰ least-developed country Members may elect not to enforce patents already granted with respect to pharmaceutical products and may choose not to grant product patents on pharmaceuticals until 2016.³¹ Footnote 6 to paragraph 2(a)(iii) of the Decision provides that the requirement imposed on eligible importing Members to issue compulsory licenses with respect to pharmaceutical products under patent in their territory “is without prejudice to Article 66.1 of the TRIPS Agreement,” which is the specific provision under which the TRIPS Council authorized non-enforcement of patents by least-developed country Members.³² It is clear, then, that in using the system established by the Decision, a least-developed country Member may elect to authorize importation based on non-enforcement of relevant patents.

It is important to note that while the least-developed country Member can avoid international law liability under the TRIPS Agreement, it must also take the necessary steps to suspend the application of relevant patents under its national law. Patents are governed by domestic law and without appropriate legislative or regulatory action, the right holder could still bring an infringement claim in national court.

Alternative 3:

This notifies of the intention to issue a compulsory license or that a compulsory license was issued. This fulfills the requirement set out in paragraph 2(a)(iii) of the Decision. Although not required, Alternative 3 is drafted to include reference to the fact that an obligation to pay remuneration in the importing country otherwise applicable pursuant to Article 31(h) of the TRIPS Agreement is waived by the Decision.

Alternative 3 does not state the grounds upon which a compulsory license has been, or may be, granted. A country may, but is not required to, state these grounds in its notification.

29. Decision of the Council for TRIPS of June 27, 2002.

30. Decision of the General Council of July 8, 2002.

31. “We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.” (Doha Declaration on the TRIPS Agreement and Public Health, paragraph 7).

32. The decision of the Council for TRIPS of June 27, 2002 (*Extension of the transition period under Article 66.1 of the TRIPS Agreement for least-developed country Members for certain obligations with respect to pharmaceutical products*) provides in its operative provisions as follows: “(1) Least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016. (2) This decision is made without prejudice to the right of least-developed country Members to seek other extensions of the period provided for in paragraph 1 of Article 66 of the TRIPS Agreement.”

Importation under the Paragraph 6 Decision

Notification by Developing Country Member

Document 3

Notification of Importation under Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health

Paragraph 1:

Based on its present evaluation of its public health needs, [Member] expects to import [quantity(ies)] of [pharmaceutical product name(s)]. However, because it is not possible to predict with certainty the extent of its public health needs [Member] reserves the right to modify the foregoing estimate as necessary or appropriate.

Paragraph 2:

Alternative 1: There is no patent on [pharmaceutical product(s) name(s)] in [Member]. This notification is made because [pharmaceutical product(s) name(s)] is (are) under patent in the country of export.

Alternative 2: [Member] [intends to issue] [has issued] a license for the importation and distribution of [pharmaceutical product(s) name(s)] without the consent of the patent holder in accordance with the provisions of the TRIPS Agreement and the Decision. Pursuant to paragraph 3 of the Decision, remuneration to the patent holder shall be determined and paid in [country of export].

(continued)

Paragraph 3:

Alternative 1: The Ministry [of ___] has examined data on the pharmaceutical sector available to it [and has consulted with experts in the pharmaceutical sector] and on that basis has determined that, excluding facilities owned or controlled by the patent holder(s), there is currently insufficient [no] capacity in the pharmaceutical sector for manufacture of the product(s) in question to meet the country's needs.

Alternative 2: The Ministry [of ___] has consulted with manufacturers in the pharmaceutical sector and has determined that, excluding facilities owned or controlled by the patent holder(s), there is currently insufficient [no] manufacturing capacity for the product(s) in question to meet the country's needs.

Alternative 3: [Member] confirms it has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for [pharmaceutical product(s)]. The methodology used to establish insufficient or no manufacturing capacities is described in the attached Annex. [Attach a suitable document. It may be entitled Annex on Methodology of Determination of Insufficient or No Manufacturing Capacities for [pharmaceutical product(s)]]

Date of notification:

Commentary**Paragraph 1**

The Decision requires notification of the names and "expected" quantities of the pharmaceutical products needed. The objective of this provision is to discourage production and export of product that might be diverted to third country markets. However, in many contexts—such as in HIV/AIDS treatment—it may be very difficult to provide concrete estimates of quantities needed over time, and the requirement of providing the expected quantities was presumably not intended to bind the exporting and importing Members to a set production amount. The objective of the System is to allow Members to meet their legitimate public health needs. For this reason, under the notification, it is recommended that a Member expressly reserve the right to revise the expected quantities to be imported.

The Decision does not establish any form or template for the notification of expected quantities. A Member might elect to indicate an aggregate "amount" of product to be imported over the duration of a license, or it might elect to indicate the amount it expects to import on a periodic basis (for example, on an annual or quarterly basis). It may be appropriate to refer to "expected quantities" on a more subjective basis, such as "a quantity of pharmaceutical product 'x' sufficient to treat 'y' patients over 'z' period." This might be a useful approach if, for example, there are different dosages and/or forms of administration of the product and the way in which orders for the product will be placed is not readily predictable.

Paragraph 2

This paragraph deals with the requirement set out in paragraph 2(a)(iii) of the Decision.

Two alternatives are provided to deal with two possible fact situations: (1) the pharmaceutical product in question is not under patent in the importing country; and (2) the importing country, in application of its patent law, will provide a compulsory license.

Alternative 1:

This is straightforward and requires no explanation. It is of interest to note, though, that even if the pharmaceutical product in question is not under patent in the importing country, the notification of actual importation under the System is still required if the conditions to which the Decision applies pertain in the exporting country (that is, the amount of product to be exported falls under the predominantly-for-the-domestic-market restriction in Article 31(b) of the TRIPS Agreement, and export of the product is not an exercise of an anticompetitive remedy under Article 31(k) of the TRIPS Agreement).

Alternative 2:

This notifies of the intention to issue a compulsory license or that a compulsory license was issued. Although not required, Alternative 2 is drafted to include reference to the fact that an obligation to pay remuneration in the importing country otherwise applicable pursuant to Article 31(h) of the TRIPS Agreement is waived by the Decision.

Alternative 2 does not state the grounds upon which a compulsory license has or may be granted. A country may, but is not required to, state these grounds in its notification.

Paragraph 3

Pursuant to paragraph 2 (a)(ii) of the Decision, an eligible importing Member that is not a least-developed country Member must establish that it has insufficient or no manufacturing capacities in the pharmaceutical sector with respect to the pharmaceutical product(s) in question according to criteria set out in Annex 1 to the Decision. Least-developed country Members are automatically deemed to have insufficient or no manufacturing capacities, so this requirement is effectively waived in respect to these countries.

Annex 1 provides in relevant part:

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

The Chairperson's statement issued in connection with the Decision further provides:

To promote transparency and avoid controversy, notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member in question had established, in

accordance with the Annex, that it has insufficient or no manufacturing capacity in the pharmaceutical sector.

The Annex refers to the sufficiency of manufacturing capacities “for the product(s) in question.” Therefore, the Annex must be understood in the context of the specific pharmaceutical inventions for which production might be undertaken locally.

So, the first question that the Member should address is not whether there is general local manufacturing capacity in the pharmaceutical sector, but whether existing capacity (assuming there is some manufacturing capacity in the pharmaceutical sector) could be adapted without material expenditure to manufacture the pharmaceutical product(s) needed in a reasonable time to provide sufficient quantities meeting appropriate quality, safety, and efficacy standards. Alternatively, if there is some capacity to produce the pharmaceutical product in question, the question is whether that capacity is sufficient to manufacture the required quantities within a reasonable time and at appropriate quality, safety, and efficacy standards.

The information to be submitted in the notification process may be a brief statement regarding the methodology used by the Member in making a determination regarding insufficient or no manufacturing capacities.³³ This might be included directly in the body of the notification, as in Alternatives 1 and 2, or it might be incorporated in an Annex (Alternative 3).

While WTO Members have discretion in their evaluation of manufacturing capacity, it is prudent to bear in mind that a determination may be subject to review at a later stage.³⁴ Hence, it is important that such determination be undertaken in a way that can be reasonably substantiated.

33. Following adoption of the Decision, the TRIPS Council delegate from India made the following statement regarding the reference in the Chairperson’s Statement to providing information regarding how insufficient manufacturing capacity is to be determined:

It had been clarified during the consultations that this did not involve provision of a great deal of technical or other information, but only the brief and concise indication of the methodology for determination of insufficient or no manufacturing capacity and the conclusions that were drawn on the basis of available data.

See General Council, Minutes of Meeting on 25, 26 and 30 August 2003, WT/GC/M/82, 17 November 2003, at paragraph 52.

34. The Council for TRIPS is required to review the functioning of the System annually. (Paragraph 6 Decision, paragraph 8) In addition, the Chairperson’s Statement provides that: (i) all notifications must be brought to the attention of the TRIPS Council at its next meeting; (ii) any matter relating to the implementation of the Decision may be brought to the TRIPS Council by any Member for “expeditious review”; and (iii) the good offices of the Director General of the WTO or the Chair of the TRIPS Council may be enlisted to resolve concerns of any Member that the terms of the Decision have not been complied with. (Chairperson’s Statement, “Third”).

Notification to Right Holder of Issuance of Compulsory License

Document 4

Notification of Issuance of Compulsory License

Paragraph 1:

Alternative 1: The [Register of Patents] held at [name and place of office of the governmental entity responsible for the grant and registration of patents] indicates that [name of patent or right holder] was issued Patent No(s) . . . [or: rights to Patent No(s) . . .] on [date].

This is to notify that [name of issuing authority] [intends to grant] [has granted] to [name of compulsory license holder] a license for the [exportation] [importation] of [pharmaceutical product(s) name(s)] without consent of the [patent] [right] holder to said [patent(s)] [right(s)] in accordance with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights, the World Trade Organization's Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health ("Decision"), and [reference to applicable domestic law].

Alternative 2: Notice is hereby given that the [issuing authority] [has authorized] [intends to authorize] [exportation] [importation] of [pharmaceutical product(s) name(s)] without the consent of any person(s) that may hold or control patent rights with respect to such product(s), in accordance with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights, the World Trade Organization's Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health ("Decision"), and [reference to applicable domestic law].

(continued)

Paragraph 2:

Pursuant to paragraph 3 of the Decision, remuneration to the patent holder(s) shall be determined and paid in [country of export].

Date of notification:

Commentary

As noted before, the requirements of Article 31(b) of the TRIPS Agreement are not waived by the Decision. These requirements include that the right holder must be notified “as soon as reasonably practicable” when a compulsory license is granted in situations of “national emergency or other circumstances of extreme urgency.” If the subject matter of a patent is used without the authorization of the patent or right holder in a case of public non-commercial use where either the government or a government contractor “without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government,” then the right holder is to be informed “promptly.” Use of the phrase “without making a patent search” indicates that the government is under no obligation to investigate the patent status of a pharmaceutical product before issuing a government use license.

A compulsory license in favor of a third party or a government use license may cover all patents that apply to the subject matter. This approach is useful because a pharmaceutical product may be covered by a number of patents and it is sometimes difficult to determine what patents, if any, may be affected by a license as to a product.

Alternative 1 may be used in the situation in which the government authority issuing the license knows the particular patent(s) that will be affected by it.

Alternative 2 may be used in the situation in which the government authority issuing the license does not know what patent(s), if any, may cover the relevant product(s). Since the government does not know what person(s) may hold patents, it cannot notify that person(s) directly. Therefore, the notice might be given to the public, for example, in a government gazette.

While this notification is strictly speaking not part of the System, a model instrument has been included here in order to draw attention to the need to satisfy this requirement of Article 31(b) of the TRIPS Agreement. It may be noted that the obligation to provide such notification applies to both the exporting and the importing Member if they both have to issue a compulsory license under the System.

There is no template for this kind of notification and there are no pre-established requirements with regard to content. Members thus retain wide freedom. If the government is not the licensee, the Member does not even have to provide the notification or information itself; it may instruct the compulsory license holder to do the necessary.

Patent Act Amendment for Exporting

Document 5

Amendment to Patent Act

For the purpose of giving effect to the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization's General Council on August 30, 2003, the [Patent Act] is amended by adding a new [Part . . .] as follows:

[Part . . .]

1. Definitions

- (a) "Decision" means the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization's General Council on August 30, 2003;
- (b) "Eligible Importing [Member] [Country]"

Alternative 1: (b) "Eligible Importing Member" means (i) any least-developed country Member of the World Trade Organization; and (ii) any Member of the World Trade Organization that has notified the Council for TRIPS of its intention to make use of the System (as hereinafter defined) as an importing country as prescribed by the Decision;

(continued)

Alternative 2: (b) “Eligible Importing Country” means (i) any least-developed country Member of the World Trade Organization; (ii) any Member of the World Trade Organization that has notified the Council for TRIPS of its intention to make use of the System as an importing country as prescribed by the Decision; and (iii) any country which is not a member of the WTO but which represents by diplomatic representation to the Minister that it will follow the System and that it has posted on a public website the notifications required under paragraphs 1(b) and 2(a) of the Decision.

- (c) “Minister” includes for purposes of this [Part . . .], and notwithstanding anything to the contrary in the [Patent Act], the [Minister of Health] who, for purposes of giving effect to this [Part], shall have authority under Section 2;
- (d) “Pharmaceutical Product” has the meaning set out in paragraph 1(a) of the Decision;
- (e) “System” means steps and/or measures prescribed by the Decision.

2. License

Subject to the provisions of Sections 3, 4, 5 and 6 of this [Part . . .] and [Sections . . . of the Patent Act], on application of any person (hereinafter “Applicant”), the Minister may grant such person a license (hereinafter “the Licensee” and “the License,” respectively) to use the subject matter of a patent regarding [a] Pharmaceutical Product(s), including a patented process regarding [that][those] Pharmaceutical Product(s), without the consent of the patent holder, for purposes of making, using (including for domestic or foreign testing and regulatory approval), offering for sale for export, selling for export and exporting such Pharmaceutical Product(s) to an Eligible Importing [Member] [Country].

3. Application

- (a) The application shall contain all information necessary to show, to the satisfaction of the Minister, that all requirements of this [Part . . .] are, or will be, complied with.
- (b) The application may [include] [be accompanied by] a representation from the Eligible Importing [Member] [Country] that the Pharmaceutical Product(s) is (are) needed to address a national emergency, other circumstances of extreme urgency, or for public non-commercial use. In such case, the application shall be treated as if such circumstance is present in [name of exporting Member] for purposes of the procedures to be followed in the granting of a license, including, *inter alia*, the waiver of any requirement for prior negotiation by the Applicant with the patent holder.
- (c) If the application is submitted by, or on behalf of, an Eligible Importing [Member] [Country], the Minister [may] [shall] presume that the Pharma-

(continued)

ceutical Product(s) subject of the application is (are) necessary to address the public health needs of that [Member] [Country]. When an application is not submitted by (or on behalf of) a governmental authority of an Eligible Importing [Member] [Country], if the Applicant submits evidence that the Eligible Importing [Member] [Country] supports the application (and the issuance by the Eligible Importing [Member] [Country] of a compulsory license in favor of the Applicant shall be conclusive evidence of such support), the Minister [may] [shall] presume that the Pharmaceutical Product(s) is (are) necessary to address the public health needs of the Eligible Importing [Member] [Country].

- (d) If the eligible importing Member is not a least-developed country Member of the World Trade Organization, the application shall be accompanied by a copy of the notification of such eligible importing Member to the World Trade Organization of its intention to make use of the System as an importer.

4. Conditions

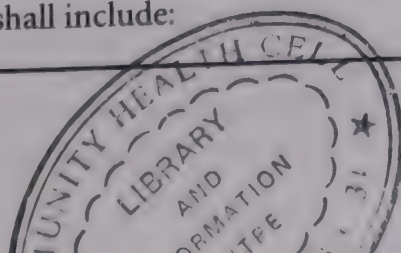
The License shall contain the following conditions:

- (a) The quantity of Pharmaceutical Product(s) made under the license shall be limited to that necessary to address the needs of the Eligible Importing [Member] [Country], including production undertaken for purposes of testing and regulatory approval. Exports of Pharmaceutical Product(s) made under the License shall be limited to the Eligible Importing [Member] [Country] and countries where testing and regulatory approval is sought.
- (b) All Pharmaceutical Products exported under the license shall be clearly identified as produced under the System through specific labeling or marking. The exported Pharmaceutical Product(s) should be distinguished through special packaging and/or special coloring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price.
- (c) The Licensee shall, prior to shipment of the Pharmaceutical Product(s) to be exported, post on its website or on a website established for the purpose by the World Trade Organization:
 - (i) The quantities of Pharmaceutical Product(s) to be supplied to each destination; and
 - (ii) The distinguishing features as required under sub-Section 4(b) above.

5. Notification to the Council for TRIPS

The Minister shall notify the Council for TRIPS, or shall cause the Council for TRIPS to be notified through appropriate channels, of any license issued under Section 2. Such notification shall include:

(continued)



- (a) The name and address of the licensee;
- (b) The Pharmaceutical Product(s) for which the License has been granted;
- (c) The quantity(ies) for which the License has been granted;
- (d) The country(ies) to which the Pharmaceutical Product(s) is (are) to be exported;
- (e) The duration of the license;
- (f) The address of the website on which the licensee will post information required by the Decision;
- (g) Any other conditions attached to the License[; and
- (h) The public website referred to in subsection 1(b)(iii)].

6. *Remuneration*

In determining remuneration to the patent holder under Section [. . .] of the [Patent Act] with respect to any license granted under Section 2, the Minister shall take into account the economic value of the authorization to the Eligible Importing [Member] [Country].

7. *Marketing Approval*

Notwithstanding anything to the contrary in [the national law(s) regarding the protection of data submitted for regulatory purposes], registration or marketing approval for Pharmaceutical Products covered by a License shall not be prevented, hindered, or delayed by claims of rights in data or for marketing exclusivity based on the patent holder's submission of regulatory data (confidential or otherwise) in [Member] or in another territory. This provision is without prejudice to requirements of the [national regulatory authority] with respect to assessment of the quality, safety, and efficacy of the Pharmaceutical Product(s).

8. *Administrative Review*

Power to review and to terminate the License shall be vested in the Minister. There shall be no right of judicial review of the continued existence of the License unless the Minister has first issued a decision upon a motivated request for termination of the License.

Commentary

Introductory Note

Provided the System is followed, the Decision waives the requirement of Article 31(f) of the TRIPS Agreement that a compulsory license shall be issued predominantly for supply of the domestic market of the Member granting the license. Model Document 5 sets out a number of provisions that may be used to implement the waiver of the export restriction in existing government use and compulsory licensing legislation.

Most patent legislation distinguishes between authorization of government use of patents, on one hand, and authorization of third party (private sector) use of patents, on

the other. Government use licensing is typically facilitated. In the discussion that follows, the terms “government use” and “compulsory licensing” (that is, third party) are sometimes used to indicate that these types of authorizations are typically addressed in separate legislative provisions (which may well include cross-referencing to common rules); otherwise, the terms “License” or “license granted under Section 2” are used to denote both government use authorizations and compulsory licenses.

The same WTO Member may be both an exporting Member and an eligible importing Member under the Decision. Members may therefore wish to consider the amendments discussed in this Document 5 (for exporting) and the following Document 6 (for importing).

There are two main approaches to addressing implementation of the Paragraph 6 Decision. One approach is to adopt a legislative provision that provides for the promulgation of regulations concerning the operation of the System. A second approach is to reflect all necessary provisions for implementation of the Decision in a legislative provision (which in most, if not all, cases would be an amendment of the Patent Act)—this is the approach that has been taken in this Guide.

A regulatory approach has the advantage of greater flexibility. The terms of the Decision (taking the form of waivers) might be varied in the course of negotiations in the WTO of a follow-on amendment to the TRIPS Agreement.³⁵ A regulatory approach should facilitate any adaptation that might be required as a result. Also, Members may wish to vary their approach to authorizations for export as experience is gained with using the System, and a regulatory approach again may facilitate adaptation.

In the event a regulatory approach is followed, a simple amendment of the Patent Act could be phrased as follows:

Where exploitation of an invention relating to a product of the pharmaceutical sector without the consent of the patent holder is sought for the purpose of exports in implementation of the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, the Minister shall follow the procedures set forth by regulation for the implementation of such Decision.

With the basic authorizing legislation thus in place, implementing regulations might follow the provisions of Model Document 5.

Definitions

The Minister.

Some patent statutes accord the power to grant government use or compulsory licenses to the Minister responsible for oversight of the patent office.³⁶ Particularly in situations where

35. Paragraph 11 of the Decision provides, in relevant part: “This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision” Progress on the preparation of the amendment has been slow.

36. This is by no means a universal practice. For example, the U.S. statute authorizing government use of patents permits any federal agency or contractor to use patents without authorization from the patent office or the patent holder. See also the U.K. Patents Act 1977, Crown Use provision referred to in the text below.

public health interests are at stake, it may be wise for Members to extend the power to authorize government use or compulsory licenses to additional Ministers, such as the Minister responsible for the public health system.

For example, it may be noted that under the Crown Use authorization in the U.K. Patents Act, “any government department and any person authorised in writing by a government department” may make use of a patent, including a patent concerning a drug or medicine, “without the consent of the proprietor of the patent” (Section 55(1), U.K. Patents Act).

The legislation and regulations of each Member are different and it will therefore be necessary to adjust the draft provision to take into account the existing structure of the patent law. The specific way “Minister” is defined in the Model Document may need to be modified within the framework of existing law, but should nevertheless provide a reminder that inclusion of the Minister of Health as one of the officials authorized to make decisions in this area is important.³⁷

The authority of the Minister should include the power to review and to terminate the compulsory license upon a duly motivated request by the patent or right holder. This is provided in Section 8 of the Model Document.

Article 31(g) of the TRIPS Agreement provides that a license issued under Article 31 is liable to termination upon motivated request if and when the circumstances that led to the granting of the license have ceased to exist and are unlikely to recur. Any such termination would have to be subject to adequate protection of the legitimate interests of the licensee.

Judicial review is made more efficient by including a clause in the legislation, as provided in the Model Document (Section 8), that requires a prior ruling by the Minister (particularly if this term includes the Minister of Health, as recommended in the Model Document) on any request or petition for termination of the compulsory license. The Minister of Health is the proper government official to make a determination regarding the continued existence or not of the public health need that gave rise to the license. Any record developed by the Minister in this determination would be of material aid in a later judicial review. Also, a requirement of prior determination by the Minister forestalls premature filings of legal actions and assures that the supply of pharmaceutical products can continue without interruption while the request for termination of the license is reviewed.

Eligible Importing Members or Countries.

As noted before, least developed-country Members of the WTO are automatically eligible to import under the System and developing country Members are eligible if they have

37. While Article 27.1 of the TRIPS Agreement provides that “patents shall be available and patent rights enjoyable without discrimination as to . . . the field of technology”, authorizing the Minister of Health to grant government use or compulsory licenses for pharmaceutical products in implementation of the Decision should not be objectionable. The WTO panel in the *Canada—Patent Protection of Pharmaceutical Products* case (WT/DS114/R, March 17, 2000) made it clear that Members may adopt measures that distinguish among patents as to different types of products for good faith reasons, observing that “discrimination” as used in Article 27.1 “is a normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment.” It should be clear that authorizing the Minister of Health to make licensing determinations as to pharmaceutical products required to meet public health needs involves a *bona fide* distinction between authorizations regarding pharmaceutical products and authorizations regarding other types of products, such as, for example, those used in automobile engines.

insufficient or no capacity with respect to the pharmaceutical products in question. However, it is foreseeable that countries that are not WTO Members will want to import pharmaceutical products under the System.

The first two industrialized countries that implemented the Decision in national law, Canada and Norway, made provision for use of the System by non-WTO Members.³⁸ Hence, Alternative 2 provides a suitable definition if an exporting country wishes to use the System to allow exports to non-WTO member countries. As did Canada and Norway, Alternative 2 provides for diplomatic assurances from the importing non-WTO Member country that it will follow the measures laid out in the Decision.

Pharmaceutical Product.

The definition of pharmaceutical product in Model Document 5 adopts the definition given in the Decision.³⁹

Paragraph 1(a) of the Decision gives the following definition of pharmaceutical product:

any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.

This definition refers to “the public health problems as recognized in paragraph 1 of the Declaration.” That paragraph of the Declaration states in its entirety as follows:

We [the Doha Ministerial Conference] recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

The definition of pharmaceutical product in the Decision is the result of nearly two years of negotiations, and so it is not surprising that it is less than a straightforward statement. While the formulation is convoluted, it also is flexible. The exact scope of “pharmaceutical sector” may perhaps lead to questions in particular cases, but it is clear that the products covered encompass health products other than medicines, and so, for example, vaccines would appear to be included. In terms of the scope of diseases to be addressed by these products, the gravity of the public health problems of developing and least-developed country Members that the Ministers recognized are the result of a wide variety of diseases, including, but not limited to, the scourges of HIV/AIDS, tuberculosis, malaria, and other epidemics.

While Members must apply the Decision in good faith,⁴⁰ the Doha Declaration evidences strong recognition and acceptance by all WTO Members of the urgent need of developing and least-developed country Members to deal with their public health prob-

38. See generally *supra*, n. 9.

39. This is also the approach adopted by Norway. The European Commission proposal and the Dutch rules refer broadly to pharmaceutical products for developing countries affected by public health problems, while the Canadian legislation uses a more restrictive approach. See *supra*, n. 9 for references to the country texts.

40. The General Council Chairperson’s statement, second paragraph (“First, Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to Paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives.”).

lems and, to that end, expressly reaffirms the right of Members to use all flexibilities in the TRIPS Agreement to the full.⁴¹ The definition of pharmaceutical product is, therefore, unlikely to be given a restrictive interpretation in practice, and it should not lead to significant problems in the implementation of the Decision.⁴²

In granting a compulsory license for the manufacture and export of a pharmaceutical product, it is important to consider that the product may be covered by a number of patents and it may be difficult for the applicant (including the government) to identify all potentially relevant patents. The authority responsible for granting the license may therefore formulate the grant so as to allow use by the applicant of all patents with respect to the identified product(s). Adequate compensation to the patent holder should take into account all patents that relate to the product(s).

The Application

National Emergency, Other Circumstances of Extreme Urgency and Public Non-Commercial Use.

It is vitally important to recognize that Article 31(b) of the TRIPS Agreement establishes two distinct procedural regimes for the grant of compulsory licenses. In the ordinary commercial case, the applicant for a compulsory license must first have sought a voluntary license from the patent holder on reasonable commercial terms and conditions, and negotiations should not have succeeded within a reasonable period of time. The second regime applies to national emergencies, other circumstances of extreme urgency, and in cases of public non-commercial use. In these latter circumstances, prior negotiation with the patent holder may be waived and notification to the patent holder may follow the grant of a license. This is sometimes referred to as the “fast-track” option under Article 31(b).

Assume that an eligible importing Member is seeking supplies of products to treat HIV/AIDS. Paragraph 5(c) of the Doha Declaration expressly acknowledges that HIV/AIDS can constitute a national emergency or circumstance of extreme urgency. If an eligible importing Member requests exports of HIV/AIDS-related pharmaceutical products, the exporting country ought to be able to rely on a representation in the compulsory license issued by the eligible importing Member that a national emergency or a circumstance of extreme urgency applies in that country with respect to HIV/AIDS and the Minister in the exporting country would therefore be justified in waiving the precondition of prior negotiation with the patent holder.

Facilitating the Approval Process.

The Decision is intended to allow countries with insufficient or no relevant manufacturing capacity to make effective use of compulsory licensing. Ordinarily authorities within a

41. In this connection, it may be recalled that the principal substantive provision of the Doha Declaration provides as follows: “We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions of the TRIPS Agreement, which provide flexibility for this purpose.” (Paragraph 4).

42. Useful further discussion of this topic may be found in Vandoren & Van Eeckhoutte, *supra*, n. 17, at 784–85; and Abbott, *supra*, n. 17.

country making a determination whether to grant a license do so based on conditions within their territory. The situation will be different in respect to applications from eligible importing Members under the Decision. The determination in the exporting country will be based on the situation in the importing country, which is where the public health problem exists. Absent exceptional circumstances, the Minister in the exporting Member should accept the determination by the eligible importing Member that its public health problems are such as to warrant use of the System and that they require importation of the pharmaceutical product(s) in question. This gives effect to the intent of the Decision, which is to allow least-developed-country Members and developing-country Members without (or with insufficient) relevant manufacturing capacity to make effective use of compulsory licensing under the TRIPS Agreement.

Not all compulsory license applications will be made by governmental authorities. It is entirely possible that private enterprises, intergovernmental organizations and NGOs will seek to procure the export of pharmaceutical products under compulsory license. In these circumstances, the question arises as to how the Minister in the exporting country should evaluate whether the authorities in the eligible importing Member support the application within the framework of the Decision. It would appear that if the authorities in the eligible importing Member have issued a compulsory license in favor of an applicant, the Minister in the exporting country should be able to rely on the grant of that license as sufficient evidence that the eligible importing Member supports the application. If such a compulsory license has not yet been granted, or need not be granted because (a) the product is not under patent in the importing country or (b) the importing country is a WTO least-developed country Member and has decided not to enforce a relevant patent, the Minister in the exporting country should be able to rely on some other evidence furnished by the eligible importing Member that it supports the application. This might, by way of illustration, be in the form of a letter from the Ministry of Health.

Conditions

Product Quantity and Destination.

Paragraph 2(b)(i) of the Decision limits production quantities and the destination of exports to the eligible importing Member(s) for which authorization is granted. Sub-Section 4(a) of the draft statute addresses this limitation. However, it also makes provision for testing and regulatory approval within and outside the exporting Member (which in any event may be deemed permitted under Article 30 of the TRIPS Agreement) because testing laboratories and regulatory approval bodies may be located within or outside the exporting Member and the eligible importing Member(s). In establishing the quality, safety, and efficacy of a medicine, a manufacturer under compulsory license may wish to submit its product for regulatory approval outside the country of manufacture or destination of export because regulatory authorities in either the exporting or importing country(ies) may base their own regulatory approvals on determinations made in third countries.

Labeling and Other Identification.

Paragraph 2(b)(ii) of the Decision imposes labeling or marking requirements so that products produced and exported under the System may be identified as such. The Chairperson's statement adopted in connection with the Decision also addresses the issue of

identification, including a clarification that active ingredients as well as finished products must be identified. Regarding active ingredients, it was understood that a label placed on a container would constitute adequate identification.⁴³

The Decision and Chairperson's statement provide that additional special identification (such as packaging, coloring or shaping) should not be required if it would have a significant impact on price, although the Chairperson's statement suggests that this would not in general be the case. This will involve a case-by-case determination.

Remuneration

Paragraph 3 of the Decision indicates that adequate remuneration to the patent holder pursuant to Article 31(h) of the TRIPS Agreement shall be paid in the exporting Member, and waived in the importing Member. For the exporting Member, adequate remuneration should be determined "taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member." The model text repeats the language of paragraph 3 of the Decision.

Although the Decision and Chairperson's statement do not provide specific guidance on how this standard is to be applied, negotiations on the Decision at the WTO were undertaken pursuant to the Doha Declaration. The Declaration emphasizes that the TRIPS Agreement should be interpreted and implemented in a manner supportive of access to medicines for all. Hence, market conditions and ability to pay in the eligible importing Member should be significant factors in determining the level of remuneration in the exporting Member.⁴⁴

Marketing Approval

Most or all countries require that a pharmaceutical product be registered and/or granted marketing approval prior to internal distribution for prescription or use. The procedures for registration and/or marketing approval vary widely, ranging from payment of a prescribed fee for registration to rigorous scientific analysis of the proposed product and dosage form. Countries without substantial pharmaceutical research infrastructure may rely on the approval procedures undertaken by foreign authorities with recognized competence in the field of pharmaceutical analysis. Recently the World Health Organization has initiated a pre-qualification program that evaluates manufacturers to determine whether the products they produce meet appropriate quality assurance standards.⁴⁵

43. This was clarified during a consultation held among WTO delegations prior to adoption of the Decision by the General Council, and is reflected in the minutes of the August 30, 2003 General Council meeting in a statement by the Indian delegation ("With regard to packaging of active ingredients, it had been clarified to India that special labeling including indication of the destination country would meet the requirements." See Minutes of Meeting of General Council of August 30, 2003, WT/GC/M/82, paragraph 52, November 13, 2003).

44. The Canadian law to implement the Paragraph 6 Decision provides that royalties will be determined in the manner to be set out in regulations and that the regulations will take into account "the humanitarian and non-commercial reasons" underlying the issuance of the compulsory license. See Bill C-9, *supra*, n. 9, at Section 21.08(2).

45. Available at <<http://mednet3.who.int/prequal>>.

Because WTO Members follow different approaches to the registration and marketing approval of medicines, each exporting Member must determine whether and how the manufacturer of products for export under the Decision will be regulated in the sense of registration and quality control. As products will be produced at the request of importers, one approach would be to rely on the pharmaceutical authorities in the importing Member for registration and testing. Alternatively, authorities in the exporting Member might require a demonstration of bio-equivalence with previously approved products, and compliance with in-country quality assurance standards. Or, the exporting and importing Member could each rely on the WHO pre-qualification procedure to inform their regulatory approval process.

Article 39.3 of the TRIPS Agreement requires Members to protect confidential regulatory submissions with respect to pharmaceutical products that utilize new chemical entities from disclosure and “unfair commercial use.” There is considerable debate among WTO Members regarding the nature of that obligation.⁴⁶

When a Member issues a compulsory license for export under the Decision, the government of the exporting Member will have made a determination that the needs of the eligible importing Member for the relevant medicine should be met. Under such circumstances, it would be inconsistent with the object and purpose of the Decision and the Doha Declaration to permit the originator company to block the implementation of the license by an independent claim that the licensee should not obtain registration or marketing approval of the product because the patent holder has previously submitted data to a regulatory authority. This would defeat the purpose of granting the compulsory license to export.

46. Certain WTO Members are of the view that Article 39.3 mandates the imposition of a period of market exclusivity in favor of the company that first submitted the data. This period is five years from the date of marketing approval in the United States and generally ten years in the European Union. See generally United States Trade Representative, *2004 Special 301 Report 4*, available at: <<http://www.ustr.gov/reports/2004-301/special310.htm>>, citing also the rules in the European Union and other countries. However, while the United States has recently negotiated a number of free trade agreements that contain intellectual property rights chapters with data protection and market exclusivity rules, in the context of agreements with non-industrialized countries that contain such provisions, it has signed side letters or similar instruments stating that the intellectual property chapter of these agreements does not prevent “the effective implementation” of the Decision. See the side letters on the free trade agreements with Bahrain and Morocco and the “Understanding Regarding Certain Public Health Measures” with the signatories of the Central America Free Trade Agreement, available at <<http://www.ustr.gov>>.

Patent Act Amendment for Importing

Document 6

Amendment to Patent Act

For the purpose of giving effect to the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization's General Council on August 30, 2003, the [Patent Act] is amended by adding a new [Part . . .] as follows:

[Part . . .]

1. Definitions

- (a) "Decision" means the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization's General Council on August 30, 2003;
- (b) "Minister" includes for purposes of this [Part . . .], and notwithstanding anything to the contrary in the [Patent Act], the [Minister of Health] who, for purposes of giving effect to this [provision], shall have authority to authorize importation under Section 2;
- (c) "Pharmaceutical Product" has the meaning set out in paragraph 1(a) of the Decision;
- (d) "System" means steps and/or measures prescribed by the Decision;
- (e) "Member" means a member of the World Trade Organization.

(continued)

2. License

- (a) Subject to [the provisions of Sections 3 and 4 of this [Part . . .] and] [Sections . . . of the Patent Act], on application of any person (hereinafter "Applicant") for authorization for the importation of a Pharmaceutical Product(s) that is (are) under patent(s) within [name of Member] and which is (are) also under patent(s) in a prospective exporting Member, the Minister may grant such person a license (hereinafter "the Licensee" and "the License," respectively) for the importation of such Pharmaceutical Product(s) without the consent of the patent holder(s) in [name of Member] from the exporting Member pursuant to an authorization to be granted by the exporting Member.
- (b) The License shall include the name(s) of the Pharmaceutical Product(s) in question and an estimate of the quantities of the Pharmaceutical Product(s) to be imported during the term of the License; provided, however, that such estimate shall not constitute a limitation on the quantities of the Pharmaceutical Product needed in [name of Member] to address the public health problem that the Pharmaceutical Product(s) is (are) intended to address.
- (c) The Minister may determine that: (i) there exists within the nation a situation of national emergency or extreme urgency with respect to the public health problem the requested imports are intended to address; or (ii) the requested imports are intended for a public non-commercial use within [name of Member]. Notwithstanding anything to the contrary in [the existing Patent Act procedures for the grant of a compulsory license], if the Minister makes such determination, any requirement for prior negotiation by the Applicant with the patent holder for a license shall be waived. In this case, the Minister shall note this fact in the body of the license so that it may be relied upon by authorities in the exporting Member.

3. Conditions [THIS SECTION ONLY TO BE USED BY ELIGIBLE IMPORTING MEMBERS THAT ARE NOT LEAST-DEVELOPED COUNTRY MEMBERS]

No License shall be granted under sub-Section 2(a) of this [Part . . .] unless:

- (a) the Minister has made a prior determination that there is insufficient or no manufacturing capacity with respect to the Pharmaceutical Product(s) in question in accordance with one of the ways set out in the Annex to the Decision; and
- (b) The Minister, or other appropriate authority of [name of Member], has notified the World Trade Organization's Council for TRIPS of [name of Member]'s intention to use the System as an importer.

(continued)

4. Notification of the World Trade Organization

Alternative 1: [The Eligible Importing Member is not a least-developed country Member and the Pharmaceutical Product is under patent in its territory]

Prior to the commencement of importation under the License, the Minister [or other appropriate authority of the Member] shall notify the World Trade Organization's Council for TRIPS of:

- (a) the grant, or intent to grant, of a [compulsory license] [government use license] in accordance with the provisions of the Decision and [relevant sections of domestic law that incorporate the provisions of Article 31 of the TRIPS Agreement];
- (b) the name(s) of the Pharmaceutical Product(s) and the expected quantities to be imported under the License; and
- (c) the determination regarding insufficient or no manufacturing capacity referred to in sub-Section 3(a) of this Part.

Alternative 2: [The Eligible Importing Member is a least-developed country Member and the Pharmaceutical Product is under patent in its territory]

Prior to the commencement of importation under the License, the Minister [or other appropriate authority of the Member] shall notify the World Trade Organization's Council for TRIPS of:

- (a) the grant, or intent to grant, of a [compulsory license] [government use license] in accordance with the provisions of the Decision and [relevant sections of domestic law that incorporate the provisions of Article 31 of the TRIPS Agreement]; and
- (b) the name(s) of the Pharmaceutical Product(s) and the expected quantities to be imported under the License.

5. No Remuneration

The License granted pursuant to sub-Section 2(a) of this Part is not subject to the payment of remuneration to the patent holder(s) within [Member] in respect of the Pharmaceutical Products for which remuneration is paid in the exporting Member in accordance with paragraph 3 of the Decision.

6. Marketing Approval

Notwithstanding anything to the contrary in [the national law(s) regarding the protection of data submitted for regulatory purposes], authorization for importation without the consent of the patent holder granted pursuant to this [Part] shall allow the importer to register and obtain marketing approval for the Pharmaceutical Product(s) from the [national regulatory authority] and shall allow the [national regula-

(continued)

tory authority] to authorize marketing approval and registration of the subject Pharmaceutical Product(s). This provision is without prejudice to requirements of the [national regulatory authority] with respect to assessment of the quality, safety, and efficacy of the Pharmaceutical Product(s).

Commentary

Introductory Note

Under the TRIPS Agreement, least-developed country Members may elect not to enforce pharmaceutical patents at least until January 1, 2016.⁴⁷ Countries that make this election should take appropriate action under their domestic law (or regulations) in order to avoid the possibility of infringement suits being brought before its courts. Model Document 6 does not address this situation.

Model Document 6 is provided for the guidance of least-developed country Members that do not make an election to forego enforcement of patents and for developing country Members. In the remainder of this Commentary, both are referred to as “importing Member.”

The patent statute of an importing Member should generally allow for importation under government use or compulsory license. In cases where the pharmaceutical products in question are not under patent in an exporting country, but are under patent in the importing country, the ordinary procedures for grant of a government use or compulsory license should be followed in the importing Member.

The System should only be used when it is necessary to request the issuance of a government use or compulsory license in an exporting Member because the needed pharmaceutical products are under patent in that country.⁴⁸

Definitions

The Minister.

The comments provided on this topic for Model Document 5 are applicable here.

The Pharmaceutical Product.

The comments provided on this topic for Model Document 5 are applicable here. The reference to “manufacture and export” in the last paragraph of these comments must be understood to refer to “import.”

47. See the comment on Document 2, paragraph 2, alternative 2 in the text, and accompanying notes.

48. It should be recalled that, if the exporting country has previously granted a government use or compulsory license predominantly for the supply of the domestic market and there is sufficient supply also to satisfy the requirements of the importing country (without that becoming the predominant supply under the license), the importing country does not need to use the System. In addition, if the exporting Member has granted a license to remedy an anti-competitive practice pursuant to Article 31(k) of the TRIPS Agreement, it need not apply the restriction on exports in Article 31(f).

License

Product Quantity.

Sub-Section 2(b) of the Model Document stipulates that the compulsory license to be issued by the importing Member specify the estimated quantity of the pharmaceutical product to be imported. It may be difficult to estimate the total needs of the country, and it may not be desirable to source all necessary imports—which could span over a number of years—from the same supplier in the same exporting country. To avoid unnecessary rigidity, it would be useful to include in the legislative provision a recognition that the amount of product stated in the license is not necessarily the total amount of product needed in the importing country. The phrasing of sub-Section 2(b) is consistent with the corresponding provisions in the notifications to the WTO provided in Model Documents 2 and 3.

Waiver of prior notification requirement.

Sub-section 2(c) of Model Document 6 authorizes the Minister to make a determination that a situation of national emergency or extreme urgency exists, or that the products are being requested for public non-commercial use. This will allow authorities in the exporting Member to waive the precondition of prior negotiation with the patent holder and thereby expedite supplies.

The option permitted under Article 31(b) of the TRIPS Agreement, to waive the requirement that an applicant for a compulsory license shall have first sought a voluntary license from the patent holder, should be reflected in the national patent law of the importing country. Sub-Section 2(c) of Model Document 6 enables this waiver notwithstanding the terms of the existing patent legislation. However, if this “fast track” option is not already part of the patent law of the importing country, an amendment to implement this option should be introduced in addition to the changes proposed in this Model Document because it may be important in situations not involving implementation of the Decision.

Notification of the World Trade Organization.

The notification set forth in Section 4 of Model Document 6 is not part of the license but is included because the giving of this notification is a condition to TRIPS-compliant authorization of a license.⁴⁹ It is not strictly necessary to provide for this in the amendment of the Patent Act (as done in Model Document 6); the notification requirement might equally well be included in any relevant regulations.

Notification to the Council for TRIPS would ordinarily be made not by the Minister (as defined in Section 1(a) of Model Document 6) but by the government representative assigned to WTO matters, such as the Ambassador to the WTO or his/her designee.

Two alternative formulations of the notification requirement are offered in Model Document 6. They only differ in that least-developing country Members do not need to include any determination regarding insufficient or no manufacturing capacity.⁵⁰

An eligible importing Member that is not a least-developed country Member must establish that it has insufficient or no manufacturing capacity in the pharmaceutical sec-

49. Decision, paragraph 2(a).

50. See *id.*, paragraph 2(a)(ii).

tor with respect to the product(s) in question pursuant to criteria set out in Annex 1 to the Decision.

Annex 1 provides as follows:

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

The Chairperson's statement adopted in connection with the approval of the Decision further provided:

To promote transparency and avoid controversy, notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member in question had established, in accordance with the Annex, that it has insufficient or no manufacturing capacity in the pharmaceutical sector.

The Annex refers to the sufficiency of manufacturing capacities "for the product(s) in question." Therefore, the Annex must be understood in the context of the specific pharmaceutical inventions for which production might be undertaken locally. The question that the subject Member should address is not whether there is general local manufacturing capacity used for pharmaceutical products but whether that existing capacity (assuming there is some capacity) could be adapted without material expenditure to manufacture the pharmaceutical product(s) needed in a reasonable time to provide sufficient quantities meeting appropriate quality, safety, and efficacy standards, or if there is some capacity to produce the pharmaceutical product in question, whether that capacity is sufficient to manufacture the required quantities within a reasonable time and at appropriate quality, safety, and efficacy standards.

The information to be submitted in the notification process may be a brief statement regarding the methodology used by the Member in making a determination regarding insufficient or no manufacturing capacities.⁵¹

While WTO Members have discretion in their evaluation of manufacturing capacity, it is prudent to bear in mind that such determination may be subject to review at a later

51. Following adoption of the Decision, the TRIPS Council delegate from India made the following statement regarding Chairperson's Statement reference to providing information regarding how insufficient manufacturing capacity is to be determined:

It had been clarified during the consultations that this did not involve provision of a great deal of technical or other information, but only the brief and concise indication of the methodology for determination of insufficient or no manufacturing capacity and the conclusions that were drawn on the basis of available data.

See General Council, Minutes of Meeting on 25, 26 and 30 August 2003, paragraph 52, WT/GC/M/82, 17 November 2003.

stage. Hence, it is important that such determination be undertaken in a way that can be reasonably substantiated.

Marketing Approval

Most or all countries require that a pharmaceutical product be registered and/or granted marketing approval prior to internal distribution for use. The procedures for registration and/or marketing approval vary widely, ranging from payment of a prescribed fee for registration to rigorous scientific analysis of the proposed product and its intended use. Countries without substantial pharmaceutical research infrastructure may rely on the approval procedures undertaken by foreign authorities with recognized competence in the field of pharmaceutical analysis. The WHO has initiated a pre-qualification program that evaluates manufacturers to determine whether the products they produce meet appropriate quality assurance standards.

Article 39.3 of the TRIPS Agreement requires Members to protect confidential regulatory submissions with respect to pharmaceutical products that utilize new chemical entities from disclosure and “unfair commercial use”. There is considerable debate among WTO Members regarding the nature of this obligation.⁵²

When a Member issues a compulsory license for import under the Decision, the government of the importing Member will have made a determination that its needs for the relevant pharmaceutical product should be met. Under such circumstances, it would be inconsistent with the object and purpose of the Decision and the Doha Declaration to permit the originator company to block the implementation of the license by an independent claim that the licensee should not obtain registration or marketing approval of the product because the patent holder has previously submitted data to a regulatory authority. This would defeat the purpose of granting the license to import. A rule that claims in data may not impede the execution of the license is stated in Section 6 of the Model Document.

To be clear, Section 6 does not address the nature of the regulatory approval methodology the importing Member adopts in terms of the quality and safety of the relevant pharmaceutical product. Thus, for example, it does not address whether and how the importing Member may determine whether a pharmaceutical product is bioequivalent to an originator product.

52. Certain WTO Members are of the view that Article 39.3 mandates the imposition of a period of market exclusivity in favor of the company that first submitted the data. This period is five years from the date of marketing approval in the United States and generally ten years in the European Union. See generally United States Trade Representative, *2004 Special 301 Report* 4, available at: <<http://www.ustr.gov/reports/2004-301/special310.htm>>, citing also the rules in the European Union and other countries. However, it appears that an exemption is being carved out for the purpose of implementing the Decision. Even though the United States has recently negotiated a number of free trade agreements that contain intellectual property rights chapters with data protection and market exclusivity rules, in the context of agreements with non-industrialized countries that contain such provisions it has signed side letters or similar instruments stating that the intellectual property chapter of these agreements does not prevent “the effective implementation” of the Decision. See the side letters on the free trade agreements with Bahrain and Morocco and the “Understanding Regarding Certain Public Health Measures” with the signatories of the Central America Free Trade Agreement, available at <<http://www.ustr.gov>>.

APPENDIXES

Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health

Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health

Decision of the General Council of 30 August 2003*

The General Council,

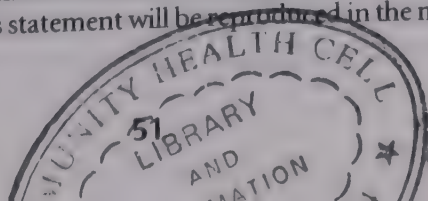
Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization (“the WTO Agreement”);

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the “Declaration”) and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in Paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

*This Decision was adopted by the General Council in the light of a statement read out by the Chairman, which can be found in JOB(03)/177. This statement will be reproduced in the minutes of the General Council to be issued as WT/GC/M/82.



Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

Decides as follows:

1. For the purposes of this Decision:

- (a) “pharmaceutical product” means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included¹;
- (b) “eligible importing Member” means any least-developed country Member, and any other Member that has made a notification² to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members and that some other Members³ have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;
- (c) “exporting Member” means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

- (a) the eligible importing Member(s)⁴ has made a notification² to the Council for TRIPS, that:
 - (i) specifies the names and expected quantities of the product(s) needed⁵;
 - (ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and
 - (iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision⁶;

1. This subparagraph is without prejudice to subparagraph 1(b).

2. It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

3. Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

4. Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in Paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

5. The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

6. This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement.

- (b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:
- (i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;
 - (ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and
 - (iii) before shipment begins, the licensee shall post on a website⁷ the following information:
 - the quantities being supplied to each destination as referred to in indent (i) above; and
 - the distinguishing features of the product(s) referred to in indent (ii) above;
- (c) the exporting Member shall notify⁸ the Council for TRIPS of the grant of the licence, including the conditions attached to it.⁹ The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

7. The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this Decision.

8. It is understood that this notification does not need to be approved by the WTO body in order to use the system set out in this Decision.

9. The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

- (i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;
- (ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in Paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

Annex

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

- (i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

- (ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

General Council Chairperson's Statement

**Excerpt from the minutes of the General Council meeting 30 August 2003
(WT/GC/M/82, 13 November 2003) (paragraph n°29)**

"The General Council has been presented with a draft Decision contained in document IP/C/W/405 to implement Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. This Decision is part of the wider national and international action to address problems as recognized in paragraph 1 of the Declaration. Before adopting this Decision, I would like to place on the record this Statement which represents several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented. I would like to emphasize that this Statement is limited in its implications to Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

"First, Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to Paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives.

"Second, Members recognize that the purpose of the Decision would be defeated if products supplied under this Decision are diverted from the markets for which they are intended. Therefore, all reasonable measures should be taken to prevent such diversion in accordance with the relevant paragraphs of the Decision. In this regard, the provisions of paragraph 2(b)(ii) apply not only to formulated pharmaceuticals produced and supplied under the system but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients. It is the understanding of Members that in general special packaging and/or special colouring or shaping should not have a significant impact on the price of pharmaceuticals.

“In the past, companies have developed procedures to prevent diversion of products that are, for example, provided through donor programmes. “Best practices” guidelines that draw upon the experiences of companies are attached to this statement for illustrative purposes. Members and producers are encouraged to draw from and use these practices, and to share information on their experiences in preventing diversion.

“Third, it is important that Members seek to resolve any issues arising from the use and implementation of the Decision expeditiously and amicably:

“To promote transparency and avoid controversy, notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member in question had established, in accordance with the Annex, that it has insufficient or no manufacturing capacities in the pharmaceutical sector.

“In accordance with the normal practice of the TRIPS Council, notifications made under the system shall be brought to the attention of its next meeting.

“Any Member may bring any matter related to the interpretation or implementation of the Decision, including issues related to diversion, to the TRIPS Council for expeditious review, with a view to taking appropriate action.

“If any Member has concerns that the terms of the Decision have not been fully complied with, the Member may also utilize the good offices of the Director-General or Chair of the TRIPS Council, with a view to finding a mutually acceptable solution.

“Fourth, all information gathered on the implementation of the Decision shall be brought to the attention of the TRIPS Council in its annual review as set out in paragraph 8 of the Decision.

“In addition, as stated in footnote 3 to paragraph 1(b) of the Decision, the following Members have agreed to opt out of using the system as importers: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, The Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

“Until their accession to the European Union, the Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia agree that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These countries further agree that upon their accession to the European Union, they will opt out of using the system as importers.

“As we have heard today, and as the Secretariat has been informed in certain communications, some other Members have agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These are the following: Hong Kong, China; Israel; Korea; Kuwait; Macao China; Mexico; Qatar; Singapore; the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu; Turkey and the United Arab Emirates.”

Attachment

(The attachment to the General Council Chairman’s Statement is marked Annex I of the document noted above)

“Best practices” guidelines

“Companies have often used special labelling, colouring, shaping, sizing, etc. to differentiate products supplied through donor or discounted pricing programmes from products supplied to other markets. Examples of such measures include the following:

- Bristol Myers Squibb used different markings/imprints on capsules supplied to sub-Saharan Africa.
- Novartis has used different trademark names, one (Riamet®) for an anti-malarial drug provided to developed countries, the other (Coartem®) for the same products supplied to developing countries. Novartis further differentiated the products through distinctive packaging.
- GlaxoSmithKline (GSK) used different outer packaging for its HIV/AIDS medications Combivir, Epivir and Trizivir supplied to developing countries. GSK further differentiated the products by embossing the tablets with a different number than tablets supplied to developed countries, and plans to further differentiate the products by using different colours.
- Merck differentiated its HIV/AIDS antiretroviral medicine CRIVAN through special packaging and labelling, i.e., gold-ink printing on the capsule, dark green bottle cap and a bottle label with a light-green background.
- Pfizer used different colouring and shaping for Diflucan pills supplied to South Africa.

Producers have further minimized diversion by entering into contractual arrangements with importers/distributors to ensure delivery of products to the intended markets.

To help ensure use of the most effective anti-diversion measures, Members may share their experiences and practices in preventing diversion either informally or through the TRIPS Council. It would be beneficial for Members and industry to work together to further refine anti-diversion practices and enhance the sharing of information related to identifying, remedying or preventing specific occurrences of diversion.”

Declaration on the TRIPS Agreement and Public Health

Declaration on the TRIPS Agreement and Public Health Adopted at Doha, Qatar, on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

- (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
- (b) Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

- (c) Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
- (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Article 31 of the TRIPS Agreement

Agreement on Trade-Related Aspects of Intellectual Property Rights

Article 31 of the TRIPS Agreement

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use⁷ of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

7. "Other use" refers to use other than that allowed under Article 30.

- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;
- (l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:
 - (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
 - (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
 - (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Compulsory Licensing for Public Health is part of the World Bank Working Paper series. These papers are published to communicate the results of the Bank's ongoing research and to stimulate public discussion.

The World Trade Organization's Declaration on the TRIP Agreement and Public Health, issued at its meeting in Doha, Qatar in 2001, represents an important achievement of the international community. It reflects a worldwide consensus on the gravity of the public health problems facing developing countries, and a recognition that international trade agreements should be used in a manner that promotes access to medicines and better public health. The August 30, 2003 decision of the WTO's General Council on the implementation of Paragraph 6 of the Doha Declaration was a tangible step forward. The decision removes some of the key constraints on the compulsory licensing of pharmaceutical products that are inherent in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

The first part of this study provides an explanation of the decision: why it was necessary and the approach it takes to overcoming the constraints of the TRIPS Agreement. This provides the reader with the necessary background to understand the model documents provided in the second part to implement the WTO decision. Four model instruments of notification are provided in the second part: three for notification of the WTO as required by the decision, and one for notification of the patent or right holder pursuant to Article 31 of the TRIPS Agreement. Most countries must amend their legislation (typically their patent law) to implement the new system. This book includes model amendment provisions both for exporting and importing countries. A detailed commentary is provided with each of the model documents.

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